IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Kenneth T. Heruth and Keith A. Miesel	Confirmation No.	8232
Serial No.:	10/825,964		
Filed:	April 15, 2004	Customer No.:	28863
Examiner:	Fangemonique A. Smith		
Group Art Unit:	3736		
Docket No.:	1023-360US01		
Title:	DETECTING SLEEP		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on March 12, 2010.

By: *Shirley A. Betlach*
Name: Shirley A. Betlach

REPLY BRIEF

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

     This is a Reply Brief responsive to the Examiner's Answer dated January 14, 2010. The deadline for filing this Reply Brief is March 15, 2010 (March 14, 2010 falls on a Sunday).

     No fees are believed to be due at this time. Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

TABLE OF CONTENTS

RELATED APPEALS AND INTERFERENCES

A Notice of Appeal for U.S. Patent Application Serial No. 11/081,786, which is a continuation-in-part of the present application, was filed on July 30, 2009. An Appeal Brief for U.S. Patent Application Serial No. 11/081,786 was filed on September 30, 2009. A Notice of Non-Compliant Appeal Brief for U.S. Patent Application Serial No. 11/081,786 was mailed on December 7, 2009. An Amended Appeal Brief for U.S. Patent Application Serial No. 11/081,786 was filed on January 7, 2010. No decisions have been rendered by the Board for U.S. Patent Application Serial No. 11/081,786.

STATUS OF CLAIMS

Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are pending and are the subject of this Appeal. The claims on appeal are set forth in Appendix A of the Appeal Brief filed on September 30, 2009.

Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. 2005/0042589 to Hatlestad et al. (hereinafter "Hatlestad") in view of U.S. Patent No. 7,207,947, to Koh et al. (hereinafter "Koh").

Claim 1-19, 24, 25, 34, 39, 41, 42, 46-52, 54, 56 and 63-71 were previously canceled.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection to be reviewed on appeal is the final rejection of claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 under 35 U.S.C. § 103(a) as being unpatentable over Hatlestad in view of Koh.

ARGUMENT

1. **Rejection of Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 as Being Obvious over Hatlestad in View of Koh**

In the Examiner's Answer to Appellant's Appeal Brief, the Examiner provided further elaboration on the Examiner's interpretation of Koh in the section titled "Grounds of Rejection" on page 5 of the Examiner's Answer, and some new arguments in the section titled, "Response to Argument" beginning on page 6 (section 10) of the Examiner's Answer. For brevity, this Reply Brief only addresses aspects of these portions of the Examiner's Answer. Accordingly, this Reply Brief is not intended to address all arguments provided in the Examiner's Answer, and Appellant requests full consideration of all arguments as set forth in the Appeal Brief.

In support of the rejection of Appellant's claims, the Examiner stated that Koh describes calculating a ratio of minute ventilation to blood carbon dioxide levels (pCO_2) of a patient to determine the current stage of sleep of the patient.[1] The Examiner also stated the Koh discloses gaining a metric through a mathematical analysis which combines the data to determine the sleep stage of the patient.[2]

The portions of Koh cited by the Examiner describe a technique for detecting circadian state and/or sleep stage based on the ratio of minute ventilation to pCO_2.[3] The detection system determines the ratio or slope of minute ventilation to pCO_2.[4] The detection system also determines an average end tidal CO_2 or pH level and determines the circadian state of the patient, e.g., whether the patient is awake or asleep, based upon the average end tidal CO_2 or pH level and/or the average ratio of minute ventilation to pCO_2.[5] If the patient is asleep, the detection system further determines the stage of sleep, such as random eye movement (REM), stage 2, or stage 3/4.[6]

---

[1] Examiner's Answer dated 1/14/10, page 5.
[2] Id.
[3] Koh, column 13, lines. 19-67 and column 14, lines 1-15.
[4] Id. at column 13, lines 46-47.
[5] Id. at column 13, lines 52-58.
[6] Id. at column 13, lines 58-60.

4

The Examiner stated that Koh discloses various non-binary quantities which assist with determining the stage of sleep of the patient.[7] The Examiner specifically referenced values of the calculated ratio of minute ventilation to pCO_2.[8] The detection system of Koh determines that the patient is awake if the ratio is greater than 1.0 or asleep if the ratio is less than or equal to 1.0.[9] As cited by the Examiner, Koh also describes determining that the patient is in stage 3/4 of sleep if the ratio is found to be in the range of 0.75 to 1.0, determining that the patient is in stage 2 of sleep if the ratio is found to be in the range of 0.50 to 0.75, and determining that the patient is in REM sleep if the ratio is less than 0.50.[10] On this basis, the Examiner asserted that the mathematical combination of the detected values described by Koh results in a non-binary probability of the patient being asleep. Appellant disagrees with this assertion.

Koh lacks any disclosure suggestive of a sleep metric that indicates a *non-binary probability* of the patient being asleep based on a physiological parameter. Instead, Koh describes making a binary determination of whether the patient is asleep, e.g., based on whether the ratio of minute ventilation to pCO_2 is greater than or less than 1.0.[11] Although Koh describes the ratio of minute ventilation to pCO_2 may have non-binary values, these values do not indicate a non-binary *probability* of the patient being asleep. Instead, any value of the ratio less than or equal to 1.0 results in a binary determination that the patient is sleeping.[12] Although the values of the ratio may be used to further determine the sleep stage of the patient if the patient is asleep, e.g., if the value of the ratio is less than or equal to 1.0,[13] the stage of sleep that the patient is in is completely unrelated to a *non-binary probability* of the patient being asleep.

The Examiner also cited column 11, lines 12-29 of Koh in support of the Examiner's assertion that Koh discloses a plurality of sleep quality metrics that each indicates a non-binary probability of the patient being asleep based on a respective physiological parameter.[14] This portion of Koh describes making a binary determination of whether a patient is asleep or awake

[7] Examiner's Answer dated 1/14/10, page 6, section 10, item 1.
[8] *Id.*
[9] Koh, column 13, lines 63-66.
[10] *Id.* at column 13, lines 66-column 14, line 3.
[11] *Id.* at column 13, lines 63-66.
[12] *Id.*
[13] *Id.* at column 13, lines 58-60.
[14] Examiner's Answer dated 1/14/10, page 7, section 10, item 2.

based on a variety of parameters that generally vary with circadian state.[15] In particular, Koh describes combining various circadian parameters together to yield a single value or metric representative of the current circadian state.[16] The metric is compared against threshold values indicative of whether the patient is asleep or awake.[17] Although each of the circadian parameters may be normalized and averaged together[18], none of the individual parameters indicates a *non-binary probability* of the patient being asleep and the combined metric does not indicate an overall *non-binary probability* of the patient being asleep. The Koh values are raw or normalized physiological parameter values, rather than probabilities.

In support of the Examiner's assertion that Koh discloses mathematically combining a plurality of sleep metric values that each indicate a non-binary probability of the patient being asleep to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep, the Examiner stated that Koh describes combining detected metrics and calculating a ratio to determine a patient's sleep stage.[19] The Examiner reasoned that the combination of the detected parameters results in an overall non-binary probability metric which indicates an overall probability of the sleep stage of the patient.[20] Appellant disagrees with this assertion.

Koh describes mathematically combining minute ventilation and pCO_2 by determining the ratio of levels of the two physiological parameters.[21] Koh also states that levels of minute ventilation and pCO_2 may be averaged over a period of time before the ratio is determined.[22] Although Koh contemplates mathematical manipulation of values of physiological parameters, Koh does not disclose or suggest mathematically combining a plurality of sleep metric values that each individually indicates a *non-binary probability* of the patient being asleep to yield an overall sleep metric value that indicates an overall *non-binary probability* of the patient being asleep. As described previously, Koh describes making a binary determination of whether the

---

[15] Koh, column 11, lines 12-29.
[16] *Id.* at column 11, lines 16-18.
[17] *Id.* at column 11, lines 26-28.
[18] *Id.* at column 11, lines 18-20.
[19] Examiner's Answer dated 1/14/10, pages 7-8, section 10, item 3.
[20] *Id* at page 8, section 10, item 3.
[21] Koh, column 13, lines 33-39.
[22] *Id.* at column 13, lines 47-52.

patient is asleep based on whether the ratio of minute ventilation of pCO_2 is greater than or less than 1.0.[23] Although levels of minute ventilation and pCO_2 may be averaged over time and combined to yield a ratio value, neither minute ventilation levels nor pCO_2 levels indicates a *non-binary probability* of the patient being asleep. Nor does the combined ratio of minute ventilation to pCO_2 indicate an overall *non-binary probability* of the patient being asleep. The Koh values are average physiological parameter values and ratios of physiological parameter values, rather than probabilities.
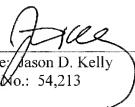
CONCLUSION

The Examiner has failed to meet the burden of establishing a *prima facie* case of obviousness with respect to claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72, and 73. In view of Appellant's arguments, the final rejection of Appellant's claims is improper and should be reversed. Reversal of all pending rejections and allowance of all pending claims is respectfully requested.

Date:

3-12-10

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8350
Facsimile: 651.735.1102

By:

Name: Jason D. Kelly
Reg. No.: 54,213

---

[23] *Id.* at column 13, lines 63-66.